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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,425	01/23/2004	Deepa Eveleigh	5151	2018

35969 7590 01/11/2007

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EXAMINER	
DUFFY, BRADLEY	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,425	EVELEIGH ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1-9 and 12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/21/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

1. The examiner of the instant application has changed here at the Patent and Trademark office. Please direct future inquiries concerning this application to Brad Duffy whose telephone number is (571) 272-9935.

2. The election filed November 8, 2006, is acknowledged and has been entered.

Applicant has elected the invention of Group V, claim 11, with the specific combination of one or more sequences being SEQ ID NOs: 2, 25, 31, 35, 49, 62, 67, 86, 89, and 96. Claim 10 is a linking claim and therefore is included with Group V. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1-14 are pending in the application. Claims 1-9 and 12-14 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. Claims 10-11 are under examination.

Election/Restrictions

5. Upon further consideration of the restriction and election requirement set forth in the Office action mailed May 11, 2006, the invention of Group V with the specific combination of sequences being SEQ ID NOs: 2, 25, 31, 35, 49, 62, 67, 86, 89, and 96 has been rejoined with inventions of Group V wherein one or more sequences are selected from 2, 25, 31, 35, 49, 62, 67, 86, 89, and 96 or any combination thereof. The restriction and election requirement separating these inventions has been withdrawn.

Information Disclosure Statement

6. The references cited in the information disclosure statement filed on August 21, 2006 have been considered.

Specification

7. The disclosure is objected to because of the following informalities:

a. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of such an improperly demarcated trademarks appearing in the specification include Bodipy™, Oregon Green™ and Texas Red™ (see page 17). Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

b. The disclosure is objected to because the disclosure refers to embedded hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified. Reference to hyperlinks and/or other forms of browser-executable code and to the Internet contents so identified is impermissible and therefore requires deletion.

An example of such impermissible disclosures appear in the specification at, for example, page 42, paragraph [201].

The attempt to incorporate essential or non-essential subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP § 608.01(p), paragraph I regarding acceptable incorporation by reference. See 37 CFR § 1.57.

c. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

8. Claims 10 and 11 are objected to as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 10 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 10-11 are indefinite because claim 10 is directed to a method for identifying a compound useful for the treatment of colon cancer; yet the claim merely recites the process of analyzing the level of expression of one or more genes prior to treatment with the compound and subsequent to treatment with the compound. There is no process step that clearly relates back to the purpose or objective of the claimed invention; consequently, the skilled artisan could not determine whether each and every process step considered essential to the practice of the claimed invention has been included in the body of the claim. Thus, in the absence of a correlative step positively relating the whole of the process to its intended use, as recited in the preamble, the claim fails to delineate the subject matter that Applicant regards as the invention with the requisite degree of clarity and particularity to permit the skilled artisan to know or

determine infringing and non-infringing subject matter and thereby satisfy the requirement set forth under 35 U.S.C. § 112, second paragraph.

Is the indication of "drug efficacy" the same as an indication that the compound is useful for the treatment of colon cancer? Drug efficacy is commonly interpreted in the art as the effectiveness and safety of a drug for treating a disease and it is unclear how a process that measures gene expression levels would be indicative of the effectiveness and safety of a drug.

(b) Claims 10-11 are indefinite for reciting "genes", in claim 10 and "genes are selected from the group consisting of SEQ ID Nos: 1-96" in claim 11. According to Genes IV (Lewin et al, Oxford University Press, page 810, 1990), a gene is defined as "the segment of DNA involved in producing a polypeptide chain; it includes regions preceding and following the coding regions (leader and trailer) as well as intervening sequences (introns) between individual coding segments (exons)". From the teachings of the specification, however, it is unclear if the nucleic acids being claimed include the defining elements of a gene. Are the nucleic acids being claimed genes that include introns and exons, or are they cDNAs, ESTs or some other type of expressed nucleic acid? Furthermore while they are selected for the group "consisting of SEQ ID NOs: 1-96", it is unclear if the nucleic acids claimed are meant to "comprise" SEQ ID NOs 1-96 or "consist of" SEQ ID NOs 1-96. Amending the claims to recite the type of nucleic acid whose expression level is being analyzed and indicating if the group consists of nucleic acids comprising the claimed SEQ IDs or nucleic acids consisting of the claimed SEQ IDs may obviate this rejection, provided no new matter is introduced.

Accordingly, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Los et al (Cytometry, 47:66-71, January 1, 2002).

Claim 10 is drawn to a method comprising analyzing the level of expression of one or more genes in a cell or tissue prior to treatment with a compound and then analyzing the level of expression of one or more genes in a cell or tissue subsequent to treatment with said compound, wherein variation in the expression level indicates drug efficacy.

Los et al teach analyzing the level of expression of 1401 genes in cells prior to treatment and subsequent to treatment with cisplatin, doxorubicin and paclitaxel (see entire document, e.g., abstract, page 69, left column and Figure 2). Los et al further teach that the variation in expression of these genes indicates drug efficacy (e.g., abstract and page 70).

Therefore, Los et al anticipate this claim.

13. Claims 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Mutter et al (US Patent 6,703,204).

Claims 10 and 11 are drawn to method comprising analyzing the level of expression of a nucleic acid comprising SEQ ID NO: 35 in a cell or tissue prior to treatment with a compound and then analyzing the level of expression of a nucleic acid comprising SEQ ID NO: 35 in a cell or tissue subsequent to treatment with said compound, wherein variation in the expression level indicates drug efficacy.

Mutter et al teach a polynucleotide having the nucleic acid sequence of SEQ ID NO: 13, which is 100% identical to SEQ ID NO: 35 of the instant application (see exhibit A attached to this office action). Mutter et al also teach analyzing the expression of SEQ ID NO: 35, prior to and after contacting cells or tissues with pharmacological agents and assessing the variation caused by the agents to determine their efficacy. (see entire document, e.g., column 11 and 12).

Therefore, Mutter et al anticipate these claims.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claim 10 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of copending Application No. 10/788,792. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 10 of copending Application No. 10/788,792 is so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application

and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claim is described supra.

Claim 10 of copending Application No. 10/788,792 is drawn to a method comprising analyzing the level of expression of one or more genes and/or gene products in a cell or tissue prior to treatment with a compound and then analyzing the level of expression of one or more genes and/or gene products in a cell or tissue subsequent to treatment with said compound, wherein variation in the expression level indicates drug efficacy.

It is noted that the preamble of copending Application No. 10/788,792 recites a method for identifying a compound useful for the treatment of breast cancer, while the instant application recites a method for identifying a compound useful for the treatment of colon cancer, however the process steps are substantially similar to the instant application and the preamble is interpreted as an intended use and is not given patentable weight.

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

16. Claim 10 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 10/675,406. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 of copending Application No. 10/675,406 anticipates claim 10 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claim is described supra.

Claim 6 of copending Application No. 10/675,406 is drawn to a method comprising analyzing the level of expression of one or more genes and/or gene products in a cell or tissue prior to treatment with a compound and then analyzing the level of expression of one or more genes and/or gene products in a cell or tissue subsequent to treatment with said compound, wherein variation in the expression level indicates drug efficacy.

It is noted that the preamble of copending Application No. 10/675,406 recites a method for identifying a compound useful for the treatment of cancer, while the instant application recites a method for identifying a compound useful for the treatment of colon cancer, however the process steps are substantially similar to the instant application and the preamble is interpreted as an intended use and is not given patentable weight.

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

Conclusion

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

STEPHEN L. RAWLINGS, PH.D.
PRIMARY EXAMINER